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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,763	06/29/2000	Hui Chen	1440.1043-001	7609

21005 7590 06/10/2003

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/10/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/606,763

Applicant(s)

CHEN ET AL.

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12,13,17,19,37-42,90 and 91 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12,13,17,19,38-42 and 91 is/are allowed.
- 6) ☒ Claim(s) 37 and 90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 12, 13, 17, 19, 37-42, 90 and 91 are pending.

Applicants' amendment filed on April 14, 2003 (Paper No. 16) is acknowledged, and applicants' response has been fully considered. Claims 17, 19 and 37-42 have been amended, and new claims 90 and 91 have been added. Claims 12, 13, 17, 19, 37-42, 90 and 91 are examined.

### **Objection Withdrawn**

2. The previous objection of claim 19 and 38-42 is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 4 in Paper No. 16.

### **Rejection Withdrawn**

### ***Claim Rejections - 35 USC § 112***

3. The previous rejection of claim 17 under 35 U.S.C. 112 second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 4 in Paper No. 16.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 37 and 90 are rejected under 35 U.S.C. 102(a) as being anticipated by Heinegard *et al.* (WO 98/46253).

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Heinegard *et al.* teach a pharmaceutical composition comprising COMP, fragments or analogs for prevention or treatment of arthritic conditions. The pharmaceutical composition comprises a purified bovine, rat or human COMP (page 6, lines 3-20; page 9, lines 14-27; page 15, lines 7-14, 23-28) and one or more arthritogenic substances such as collagen II, IX or XI, or aggrecan (page 15, lines 1-6; claims 37 and 90).

In response, applicants indicate the amended claim 37 is directed to a composition comprising purified COMP in a calcium-replete conformation, while the composition of Heinegard *et al.* comprises COMP purified in the presence of EDTA rather than calcium, thus the composition of Heinegard *et al.* comprises COMP of a different conformation from the COMP in the presence of calcium (page 5 of the response). The argument is not found persuasive because Heinegard *et al.* not only teach the purification of rat COMP in the presence of EDTA, it also indicate COMP may be isolated from naturally isolated material as described in Hedbom *et al.*, J. Biol. Chem. 267, 6132-6136 (1992) (page 15, lines 7-14), which does not include EDTA in the buffer used for purification of bovine COMP (page 6132, right column, Fig. 1), thus COMP of Heinegard *et al.* may also be the COMP in a calcium-replete conformation, which meets the criteria of claim 37.

### ***Conclusion***

5. Claims 37 and 90 are rejected. It appears claims 12, 13, 17, 19, 38-42 and 91 are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CHK*  
Patent Examiner

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June 7, 2003

*Christopher C. F. Low*  
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